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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,884	01/21/2000	Terry R. Colbert	P04348US0-PHI-1194	6401

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EXAMINER
KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	15

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,884	COLBERT, TERRY R.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,20,21,33,34,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,20 and 33* is/are allowed.

6)☒ Claim(s) *6-8,21,34,41 and 42* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *14* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The finality of the Office action mailed 5 March 2003 is herein withdrawn, and new rejections are put forth. Upon further consideration, a new ground(s) of rejection is(are) made herein.

2. The Amendment After Final response filed 13 May 2003 has been entered into the file. Claim 9-19, 22-32 and 35-40 have been cancelled. Claims 1-8, 20, 21, 33, 34, 41 and 42 are pending.

3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or Remarks filed 13 May 2003.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claim 5 is objected to because of the following informalities:

Claim 5 is unclear as to where the tissue culture of regenerable cells is produced from, the phrase -- prepared from cells or protoplasts -- after "regenerable cells" would obviate this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 6, 7, 8, 21, 33, 34, 41 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 6, lines 1-2, the phrase "the cells or protoplasts of said cells" lacks proper antecedent basis in claim 5. Amendment of claim 5 as suggested above and amendment of claim 6 to recite -- wherein the cells or protoplast are isolated from -- would obviate this rejection.

At claim 7, line 2, the phrase "capable of expressing all" is indefinite because it is unclear when or under what conditions the morphological and physiological characteristics are expressed. Amending said phrase to read -- having all of -- would obviate this rejection.

Claims 8 and 21 are indefinite because the maize plant of claim 2 or 20, respectively, is not male sterile, hence claims 8 and 21 are improperly dependant on claims 2 and 20 respectively. Also, it is unclear what is encompassed by "genetic factor", and "further comprises" is improperly used since "comprises" was not previously recited. Amending said claims to read -- A male-sterile maize plant produced from the maize plant of claim 2 (20) wherein said male-sterile plant comprises a transgene conferring male sterility -- would obviate this rejection.

At claim 33, "developing from the cross a hybrid maize plant" is indefinite because it is unclear what is encompassed by "developing". It is recommended that the phrase be amended to recite -- producing hybrid maize seed --, and that an additional method step be added that recites -- growing a hybrid maize plant from said seed --. Further, "deposited as PTA-1304 and "deposited as PTA-4289" are indefinite, because it is believed that seed, not plants were deposited.

Claim 34 is indefinite because the method steps "obtaining" and "applying" do not state positive method steps by which one of skill in the art could make an inbred maize plant as claimed. Replacing the term "obtaining" with -- isolating one or more haploid cells from --, and the phrase "applying double haploid methods to obtain a plant that" with -- producing a double haploid plant from said cells wherein said double haploid plant --, is suggested. In addition, at line 3, the term "essentially" renders the claim indefinite because the nature of double haploid methods by their nature produce a plant that is homozygous at every locus, hence what the metes and bounds of the term "essentially" is unclear.

At claim 41, line 2, the phrase "genetic factor" is indefinite because it is unclear what the metes and bounds of this limitation are. The specification at pages 2-3 only teach use of transgenes to confer male sterility on a exemplified male-fertile plant, the use of cytoplasmic male sterility does not appear to be possible because Applicant discloses that the exemplified 33T17 hybrid maize plant is male-fertile. Claim 42 is also indefinite because it does not remedy the indefiniteness of claim 41.

7. Claims 8, 21, 41 and 42 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a maize plant comprising a genetic factor conferring male sterility and a method of making same.

Applicant describes a male-fertile hybrid maize plant 33T17 produced from male-fertile inbred maize parents GE515488 and GE534625 (page 7 of the specification).

Applicant does not describe a male-sterile maize plant or genetic factors that confer male sterility as broadly claimed. Applicant only describes transgenes that confer male-sterility and a method of making a male-sterile, transgenic maize plant by transformation of the disclosed hybrid maize plant with said transgene(s) (pages 2-3 of the specification). In addition, Applicant does not describe hybrid maize plants obtained by backcross introgression of a male-sterility trait, or those traits that are brought in by the outcross and that remain during the selection for male-sterility.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

8. Claims 8, 21, 41 and 42 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a male-sterile plant comprising a transgene that confers male-sterility produced from the disclosed 33T17 hybrid maize plant by transformation with a transgene conferring male sterility, does not reasonably provide enablement for a male-sterile plant comprising a "genetic factor" conferring male sterility, including plants produced by other methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a maize plant comprising a genetic factor conferring male sterility and a method of making same.

Applicant teaches a male-fertile hybrid maize plant 33T17 produced from male-fertile inbred maize parents GE515488 and GE534625 (page 7 of the specification).

Applicant only teaches how to make a male-sterile, transgenic maize plant from the exemplified hybrid maize plant (pages 2-3 of the specification). Applicant does not teach how to introduce a "genetic factor" that confers male sterility by other methods.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant does not teach a male-sterile maize plant in the instant specification. Applicant's exemplified hybrid 33T17 maize plant appears to be male-fertile, as are the exemplified parental inbred lines used to make said hybrid maize plant. The issue is how to make the claimed plant and enablement of said plant within the breadth of the claimed invention. Production of a cytoplasmic male-sterile maize plant, without direct introduction of a transgene, requires crossing an elite fertile maize plant with a cytoplasmic male-sterile maize plant and backcrossing progeny plants with the elite fertile maize plant as the male parent, since cytoplasmic genetic inheritance is only through the female parent. Applicant admits that the possibility of reproducing an exemplified genotype is highly unpredictable because of the large number of loci that

control the expression of useful traits (pages 6-7 of the specification). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make a male-sterile hybrid maize plant from the exemplified male-fertile inbred parent maize plants or the exemplified 33T17 hybrid maize plant that does not comprise genetic material or other traits not in the exemplified hybrid maize plant as broadly claimed without using plant transformation technology. Such a male-sterile plant produced by backcrossing would comprise other genes not associated with male sterility and would not be the exemplified inbred parental maize plants or the exemplified hybrid 33T17 maize plant, for which Applicant has enabled one of skill in the art to make and use by means of a deposit of biological material.

Conclusion

9. This Office action is non-final.

10. The claims are free of the prior art, which neither teaches nor suggests the exemplified 33T17 hybrid maize plant or method of using said maize plant.

11. Claims 6-8, 21, 34, 41 and 42 are rejected.

12. Claim 5 is objected to.

13. Claims 1-4, 20 and 33 are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D.
16 June 2003